10903 New Hampshire Avenue
Silver Spring, MD 20993

WARNING LETTER

October 30, 2017

Aaron Dallek, CEO
Opternative, Inc.
175 N. Ada Street
Chicago, IL 60607

Re: On-Line Opternative Eye Examination Mobile Medical App Device
Refer to CMS# 532477

Dear Mr. Dallek:

The United States Food and Drug Administration (FDA) has learned that your firm is marketing the On-Line Opternative Eye Examination Mobile Medical App device in the United States without marketing clearance or approval, in violation of the Federal Food, Drug, and Cosmetic Act (the Act).

Under section 201(h) of the Act, 21 U.S.C. § 321(h), this product is a device because it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body.

FDA has reviewed your website and determined that the On-Line Opternative Eye Examination Mobile Medical App device is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because you do not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g). The On-Line Opternative Eye Examination Mobile Medical App Device is also misbranded under section 502(o) the Act, 21 U.S.C. § 352(o), because you did not notify the agency of your intent to introduce the device into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). For a device requiring premarket approval, the notification required by section 510(k) of the Act, 21 U.S.C. § 360(k), is deemed satisfied when a PMA is pending before the agency, 21 C.F.R. 807.81(b).

On June 15, 2016, during a meeting held at our Agency, your firm was notified by the Office of Compliance and the Office of Device Evaluation that the On-Line Opternative Eye Examination Mobile Medical App device requires a premarket submission in order to allow the Agency to evaluate its safety and effectiveness.

The kind of information you need to submit in order to obtain approval or clearance for your device is described on the Internet

at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm. The FDA will evaluate the information you submit and decide whether your product may be legally marketed.

For a device requiring premarket approval, the notification required by section 510(k) of the Act, 21 U.S.C. § 360(k), is deemed satisfied when a PMA is pending before the agency. 21 CFR 807.81(b). The kind of information that your firm needs to submit in order to obtain approval or clearance for the device is described on the Internet at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm. The FDA will evaluate the information that your firm submits and decide whether the product may be legally marketed.

Our office requests that Opternative, Inc. immediately cease activities that result in the misbranding or adulteration of the On-Line Opternative Eye Examination Mobile Medical App device, such as the commercial distribution of the device through your online website.

Your firm should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties. Also, federal agencies may be advised of the issuance of Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Please notify this office in writing within fifteen business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (which must address systemic problems) your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this Warning Letter.

Your firm's response should be sent to:

Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance
Field Inspections Support Branch
White Oak Building 66, Rm 3540
10903 New Hampshire Ave.
Silver Spring, MD 20993

Refer to the identification number CMS# 532477 when replying. We remind you that only written communication is considered as official. If you have any questions about the contents of this letter, please contact: Shanika Booth at 301-796-5771.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm. It is your firm's responsibility to ensure compliance with the applicable laws and regulations administered by FDA.

Sincerely,
/S/

CAPT Sean M. Boyd, MPH, USPHS
Deputy Director for Regulatory Affairs
Office of Compliance
Center for Devices and Radiological Health